FBI Laboratory
Practices for Addressing a Nonconformity

1 Purpose

These practices specify steps and requirements to ensure a nonconformity is addressed within the specified timeframe, the effect(s) on prior work or records is remediated, if appropriate, and the possibility of recurrence is minimized, in order to bring about continuous improvement. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

2 Scope

These practices apply to FBI Laboratory personnel who are involved in identifying and addressing nonconformities. Additionally, personnel may follow these practices when handling a complaint.

3 Practices

3.1 Nonconformity

3.1.1 A nonconformity is the non-fulfillment of a requirement. FBI Laboratory personnel, internal or external customers, and/or external auditors/assessors may identify a situation or condition where a concession, correction, or corrective action is required. The appropriate technical management in collaboration with the unit QA representative will evaluate the situation or condition when it is reported. The significance of a nonconformity will be evaluated and categorized as requiring a concession, a correction, or a corrective action.

3.1.2 Responses to Nonconformity

The responses to a nonconformity are defined as:

- A **concession** is an acknowledgement that a nonconformity has been detected, and the nonconformity will not be corrected.
- A **correction**[1] is an action to eliminate a detected nonconformity.
- A **corrective action** is an action to eliminate the ***cause*** of a detected nonconformity.

[1] Correction as defined in these practices does not refer to a correction that occurs at the time of generation of case records involving an initialed single strikeout where the correction is entered alongside, or those similar corrections tracked in electronic case records.

3.2 Concessions and Corrections

If the evaluation indicates the potential impact of the nonconformity is low and:

- the activity or work is deemed acceptable or uncorrectable and will only be acknowledged, then a **concession** is appropriate.
- the activity or work is deemed correctable, it will be corrected, then a **correction** is appropriate.

Concessions and corrections do not require a root cause analysis of the situation or condition.

3.2.1 Notification, Records, and Review of Concessions and Corrections

3.2.1.1 The person identifying a nonconformity that will be handled as a concession or a correction will notify the appropriate Unit Chief(s) and/or Supervisor(s) at the time the nonconformity is identified. The Quality Manager does not need to be notified when a situation or condition will be handled as a concession or correction.

3.2.1.2 Units will record concessions and/or corrections in a centralized location (e.g., binder, spreadsheet). Records will include specific information to allow for a unit, discipline, and/or category of testing to determine any trends that may need to be addressed through a corrective action and/or document revisions. Unit Chiefs and Technical Leaders will ensure concession and correction records are reviewed, at a minimum on an annual basis, to determine what, if any, trends are occurring and may require corrective action. The review of corrections and concessions will be recorded and will include a notation as to whether any trends were identified.

3.3 Corrective Actions

If the evaluation of the nonconformity indicates the situation or condition is adverse to quality (e.g., recurrence is possible, potential impact is increased), then corrective action will be taken. A *Corrective Action Request* (7-254) (Appendix A) will be initiated. Corrective actions must begin with root cause analysis of the situation or condition.

3.3.1 Notification of Situations or Conditions Adverse to Quality Resulting in a Corrective Action

3.3.1.1 If a situation or condition exists that may potentially be adverse to quality and a corrective action may be warranted, the person identifying the situation or condition will notify their Unit Chief at the time it is identified.

3.3.1.1.1 For technical matters the person identifying the situation or condition will also notify the Technical Leader at the time it is identified.

3.3.2 If the Unit Chief and/or Technical Leader determines the situation or condition is potentially adverse to quality and a corrective action may be warranted, they will ensure other

impacted Unit Chief(s) and the Quality Manager are notified in writing at that time. The notification to the Quality Manager will be retained.

3.3.3 The Quality Manager does not need to be notified when a situation or condition has progressed to a personnel performance issue, unless the situation also involves steps taken in accordance with these practices.

3.4 Completing a *Corrective Action Request*

3.4.1 The *Corrective Action Request* is used to record the root cause analysis and subsequent corrective actions. This form identifies the situation or condition, the requirement source(s), the specific requirement(s), the person who is responsible for managing the corrective action, the root cause(s) of the situation or condition, the action step(s), and the expected completion date(s) of each action step(s).

3.4.1.1 Upon notification to the Quality Manager, the Unit Chief will ensure their unit personnel initiate a *Corrective Action Request* in the Quality Assurance Corrective Action Request (CAR) database. Refer to the Quality Assurance (QA) Program Procedures for Entering Data in the Quality Assurance Corrective Action Request (CAR) Database for entering the information described below.

3.4.1.2 The Quality Manager and/or a QA Specialist will evaluate the situation or condition entered into the CAR database and determine if the *Corrective Action Request* is appropriate. If the Quality Manager and/or QA Specialist determine a corrective action is not warranted, the unit will be notified and the entry in the CAR database will be closed out. A comment will be added to the CAR database as to why the corrective action was not necessary.

3.4.1.3 To minimize the impact of the nonconformity, *Corrective Action Requests* must be issued within 45 calendar days of being identified as potentially adverse to quality. A *Corrective Action Request* will be considered issued when the root cause(s) and action step(s), with completion dates for each action step, are approved by the Quality Manager.

3.4.2 The Quality Manager will determine when a nonconformity is significant and ensure the notification requirements of the applicable accrediting body(ies) are met (e.g., ANAB requires notification within 30 days of Quality Manager determining it as significant).

3.4.3 Root Cause Analysis

Root cause analysis is important in preventing the recurrence of a nonconformity. The person responsible for managing a corrective action will investigate and determine the root cause(s).

The root cause(s) may be determined by following a cause-and-effect model (e.g., 5 whys, fishbone diagram, cause map) that evaluates potential causal factors. Potential causal factors should be evaluated, as appropriate, in the broad areas of equipment, personnel (e.g., work schedules, deployments, staffing), methods, environment, evidence, materials and supplies,

budget, previous occurrences, and/or customer complaints. Refer to the FBI Laboratory Division BUNET quality system documents webpage Resources tab for the evaluation of potential causal factors.

3.4.4 Action Steps

Action steps must be specific, measurable, achievable, relevant, and time bound. Action steps will also be proportional to risks and opportunities. Objective evidence of completion of each action step(s) will be collected and retained. Depending on the nature of the nonconformity, appropriate action steps may include:

- Notification to the contributor(s).
- Review of, and correction to, any relevant casework and/or DNA databasing.
- Additional review of work before release of reports and/or DNA *Match Confirmation Letters*.
- Issuance of follow up reports and/or DNA *Match Confirmation Letters*.
- Reassignment of duties.
- Remedial training.
- Revisions to policies, practices, procedures, and/or forms.
- Adoption of additional quality control measures.
- Indefinite removal of the person(s) from casework or DNA databasing.

The appropriate Technical Leader and Unit Chief(s) will authorize the resumption of casework or DNA databasing.

3.4.5 Accepting Corrective Action Steps

3.4.5.1 The appropriate Unit Chief(s) will sign and date the form in the space labeled "Steps Approved by Unit Chief" indicating approval of the action steps listed and the expected completion date for each action step.

3.4.5.1.1 Additionally, for technical matters, the appropriate Technical Leader will sign and date the form in the space labeled "Steps Approved by Technical Leader (for technical matters)" indicating approval of the action steps listed and the expected completion date for each action step.

3.4.5.2 The Quality Manager and/or a QA Specialist will review the *Corrective Action Request* to determine its adequacy, acceptability of the planned action step(s), and the expected completion date(s) of each action step(s). If the request is determined to be less than adequate, the person responsible for managing the corrective action will be required to amend the *Corrective Action Request*. When approved, the Quality Manager will sign and date in the space labeled "Reviewed and Approved By" indicating the acceptance of the root cause(s) and action step(s). A QA Specialist will forward a signed copy to the person responsible for managing the corrective action. The person responsible for managing the corrective action will ensure each action step is implemented by the expected completion date.

3.4.6 Completed Corrective Action Steps

A QA Specialist will liaise with the person responsible for managing the corrective action to determine if each action step is complete by its expected completion date.

3.4.6.1 Once all of the action step(s) have been completed, the person responsible for managing the corrective action will ensure objective evidence in support of the completion of each action step is provided to a QA Specialist. A QA Specialist will review the objective evidence. A QA Specialist will sign and date in the space labeled "Actions Completed" when the objective evidence indicates each action step is completed.

3.4.7 Verification of Effectiveness of a Corrective Action

A QA Specialist will ensure the effectiveness of the corrective action(s) is verified. This may be accomplished by reviewing objective evidence of implementation, or it may be necessary to verify the effectiveness by other methods, which may include a review of affected work, additional audits, and/or interviews of affected personnel.

3.4.7.1 When the effectiveness of the corrective action(s) has been verified, a QA Specialist will sign and date the space labeled "Verified Effectiveness." A notation of what records were reviewed, or a copy of the records reviewed, to verify effectiveness will be retained.

3.4.7.1.1 For some corrective actions, the effectiveness of the action step(s) cannot be verified. In this instance, a QA Specialist will mark the space labeled "Verified Effectiveness" as "not applicable."

3.4.7.1.2 If a QA Specialist determines an action step(s) was not effective, a course of action will be recommended to the Quality Manager who will determine the next steps taken.

3.4.8 Closing Out a Corrective Action

3.4.8.1 The Unit Chief(s), or for technical matters the appropriate Technical Leader(s), will sign and date in the space labeled "Unit/Discipline/COT Approved" indicating approval for close out of the *Corrective Action Request*.

3.4.8.2 The Quality Manager will sign and date the *Corrective Action Request* in the space labeled "Approved" indicating approval for close out of a corrective action.

3.4.8.3 The Laboratory Director will sign and date the space labeled "Closed Out" thereby closing the *Corrective Action Request*.

3.4.8.4 The original *Corrective Action Request* will be retained in the FASU. A copy of the signed, closed out *Corrective Action Request* will be forwarded to the person managing the corrective action.

3.5 Tracking Progress of *Corrective Action Requests*

QA Specialists will track the progress of *Corrective Action Requests.*

3.5.1 All requests for information from a QA Specialist to the person managing the corrective action or other appropriate individual must be answered in a timely manner (e.g., within one to two days) and with the appropriate information/objective evidence. Issues related to the handling of a *Corrective Action Request* including non-responsiveness to requests for information or lack of progress on a corrective action may be elevated to the Section Chief of the person managing the corrective action by the Quality Manager.

3.5.2 The Quality Manager will provide updates on open *Corrective Action Requests* at regularly scheduled meetings with Executive Management.

4 Records

The following records will be generated and/or retained unless specified otherwise through one accreditation cycle as a result of these practices:

- Original *Corrective Action Requests* and associated records (e.g., notification to Quality Manager, objective evidence of action step(s) completion, accrediting body notification) will be maintained in FASU.
- Other associated records will be maintained by the units.
- Unit concession and correction records, including annual reviews, will be maintained by the unit.

5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

FBI Laboratory Operations Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17020 - Conformity Assessment - Requirements for the Operation of Various Types of Bodies Performing Inspection, International Organization for Standardization, Geneva, Switzerland, 2012.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Okes, D., *Root Cause Analysis The Core of Problem Solving and Corrective Action*, American Society for Quality, Quality Press, Milwaukee (2009).

Robitaille, D. *Root Cause Analysis Basic Tools and Techniques*, Paton Professional, Chico (2004).

Rev. #	Issue Date	History
12	06/03/19	Expanded scope in section 2 to include handling complaints. Changed from 30 to 45 days in section 3.4.1.3. In section 3.4.4 added requirement for action steps to be proportional to risks and opportunities and statement that Technical Leader and Unit Chief(s) will authorize resumption of casework or DNA databasing. Updated requirement in section 3.4.5.1 regarding appropriate Unit Chief approval of action steps. In section 3.4.7, removed "verification" to avoid conflicting with LOM definition for this term. Removed requirement for providing monthly status updates to affected Unit Chiefs. Updated list of references in section 5. Revised *Corrective Action Request* in Appendix A.
13	12/21/20	Grammatical and formatting changes throughout 3.1.1 – Added: in collaboration with the unit QA representative 3.2 – Replaced not acceptable with correctable 3.2.1.1 – Reworded for clarity 3.4.1.1 – Updated references 3.4.1.3 – Added: calendar days 3.4.4 – Reworded for clarity; Replaced amended, supplemental, and/or superseding reports with follow up reports 3.4.8.1 – Added: Unit/Discipline/COT Approved 4 – Removed or five years, whichever is longer 5 – Updated references

Redacted - Signatures on File

Approval

Laboratory Director Date: 12/18/2020

Quality Manager Date: 12/18/2020

Appendix A: *FBI Laboratory Corrective Action Request* (7-254)

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